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PROTOCOL

Effectiveness of Reiki practice in diabetic pregnant women: randomized clinical trial protocol

Efectividad de la práctica de Reiki en embarazadas diabéticas: protocolo de ensayo clínico aleatorizado

Efetividade da prática do Reiki em gestantes diabéticas: protocolo de ensaio clínico randomizado

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Abstract

The aim was to outline the protocol of a randomized clinical trial (RCT) with the objective of identifying the effectiveness of the practice of Reiki in diabetic pregnant women. 150 pregnant women with diabetes were included and randomized into three groups: control/placebo group (mimicking of Reiki therapy), intervention (with face-to-face Reiki therapy technique) and remote intervention (with remote Reiki therapy) in the period of March from 2016 to December 2018. The intervention comprised seven Reiki sessions compared to the simulation of laying on of hands, in person or at a distance. Quality of life and anxiety will be measured, in addition to perinatal outcomes such as: gestational age at birth, Apgar score, birth weight, classification of gestational age at birth (term or preterm), classification of newborn weight by gestational age, type of care (joint accommodation, nursery and NICU) and perinatal death. Statistics will comprise a descriptive analysis with the calculation of mean and standard deviation for quantitative variables and frequencies and percentages for categorized variables. The literature has few works on Reiki in obstetrics, highlighting the need to carry out studies that introduce integrative and complementary therapies in Brazilian public health.

Descriptors: Complementary Therapies; Therapeutic Touch; Diabetes Mellitus; Pregnancy in Diabetics; Randomized Controlled Clinical Trial.

Resumén

El objetivo fue perfilar el protocolo de un ensayo clínico aleatorizado (ECA) con el objetivo de identificar la efectividad de la práctica de Reiki en embarazadas diabéticas. Se incluyeron 150 mujeres embarazadas con diabetes y se aleatorizaron en tres grupos: grupo control / placebo (imitando la terapia de Reiki), intervención (con técnica de terapia de Reiki cara a cara) e intervención remota (con terapia de Reiki remota) en el período de marzo de 2016 a diciembre de 2018. La intervención comprendió siete sesiones de Reiki frente a la simulación de imposición de manos, en persona o a distancia. Se medirá la calidad de vida y la ansiedad, además de los resultados perinatales como: edad gestacional al nacer, puntaje de Apgar, peso al nacer, clasificación de la edad gestacional al nacer (a término o prematuro), clasificación del peso del recién nacido por edad gestacional, tipo de cuidados (acomodación conjunta, guardería y UCIN) y muerte perinatal. La estadística comprenderá un análisis descriptivo con el cálculo de media y desviación estándar para variables cuantitativas y frecuencias y porcentajes para variables categorizadas. La literatura tiene pocos trabajos sobre Reiki en el área de la obstetricia, destacando la necesidad de realizar estudios que introduzcan terapias integradoras y complementarias en la salud pública brasileña.

Descriptores: Terapias Complementarias; Toque Terapéutico; Diabetes Mellitus; Embarazo en Diabéticos; Ensayo Clínico Controlado Aleatorizado.

Resumo

Objetivou-se delinear o protocolo de um ensaio clínico randomizado (ECR) com o objetivo de identificar a efetividade da prática do Reiki em gestantes diabéticas. Foram incluídas 150 gestantes diabéticas que foram randomizadas em três grupos, sendo: grupo controle/placebo (mimetização da terapêutica Reiki), intervenção (com a técnica terapêutica Reiki presencial) e intervenção à distância (com a terapêutica Reiki à distância) no período de março de 2016 a dezembro de 2018. A intervenção compreendeu em sete sessões de Reiki em comparação a simulação de imposição das mãos, de forma presencial ou à distância. Serão mensurados a qualidade de vida e ansiedade, além de desfechos perinatais como: idade gestacional ao nascimento, índice de Apgar, peso ao nascer, classificação da idade gestacional ao nascimento (termo ou pré-termo), classificação do peso do recém-nascido por idade gestacional, tipo de atendimento (alojamento conjunto, berçário e UTI Neonatal) e morte perinatal. A estatística compreenderá uma análise descritiva com o cálculo de média e desvio padrão para variáveis quantitativas e frequências e percentuais para as variáveis categorizadas. A literatura dispõe de poucos trabalhos sobre Reiki na área de obstetrícia, evidenciado a necessidade da realização de estudos que introduzam as terapias integrativas e complementares na saúde pública brasileira.

Descritores: Terapias Complementares; Toque Terapêutico; Diabetes Mellitus; Gravidez em Diabéticas;

Introduction

Pregnancies complicated by diabetes mellitus (DM) are associated with increased maternal and neonatal complications[1]. The most routine complications include macrosomia with a consequent increased risk of birth trauma and intrapartum hypoxia/asphyxia, high rates of cesarean section, delayed pulmonary maturation and metabolic disorders at birth, including hypoglycemia, hypocalcemia and hypomagnesemia[2].

Regardless of the diagnosis of the type of diabetes or whether mild hyperglycemia occurs, the perinatal outcome is related to maternal metabolic control. The improvement in maternal and perinatal outcomes in diabetic pregnant women, described in the literature in recent decades, is related to obtaining maternal euglycemia[3-4]. To treat and maintain strict blood glucose control, pregnant women are treated in an outpatient clinic or with frequent and short hospitalizations[5-7].

In frequent and short hospitalizations and in prenatal consultations, maternal glycemic levels, and the need for inclusion and/or changes in the dose of insulin are analyzed. For gestational diabetics, this type of intensive insulin control can preserve the maternal pancreatic beta cell from exhaustion and reduce the possibility of future development of type diabetes[8].

In this sense, complementing the medical treatment of pregnant diabetic women, alternative therapies can be used together with allopathic treatment to improve the quality of life. There are "Integrative and Complementary Practices in Health" (PICS)[9], such as meditations, oriental body therapies (Acupuncture, Yoga, Ayurveda, and Reiki), anthroposophical therapies, among many others.

Therapists of integrative and complementary practices in health aim to provide more humanized care through self-awareness and perception, as well as the context around them. The gestational stage of the embryo is essential for the formation of the individual, not only in the material sense of the new family, but also in changing the routine, family habits and rhythm that this family will experience[10]. To bring this balance to both the pregnant woman and the newborn, it is necessary to understand the entire vital process of both, in health and in disease. Therefore, pregnant women who have diabetes before pregnancy and gestational diabetes are somehow out of energy balance, which can have consequences on their quality of life and well-being.

Currently, the world population is looking for new forms of health treatment, a way that is more natural and less invasive. Due to this, integrative and complementary practices in health have been gaining more and more space around the world, given the humanized and holistic view, as well as respect for the routines and rhythms of each person's life. Such treatments aim at the energy balance of people and are integrated with allopathic health[11].

In this sense, the practice of Reiki is being increasingly diffused as one of the integrative and complementary practices in health to promote balance between body, mind and spirit. Reiki is a hands-on technique whose aim is to use mantras and mantras to promote energy balance in the body, mind, and spirit.

Literature lacks the study of Reiki in obstetrics, as there is a notorious scarcity on the subject. Therefore, this randomized clinical trial (RCT) protocol aims to assess the effectiveness of the therapeutic modality of laying on of hands (Reiki) in diabetic pregnant women.

Methodology

Study design

This study protocol proposes a randomized clinical trial comparing the effectiveness of reiki in diabetic pregnant women. This study follows the Consolidated Standards of Reporting Trials (CONSORT)[12] recommendations to ensure transparency and methodological rigor in the writing of the study.

The study is being developed at the Center for Investigation of Perinatal Diabetes, Hospital das Clínicas, Faculty of Medicine of Botucatu (CIDP/HC/FMB – Unesp), characterized as a tertiary care center responsible for treating high-risk pregnant women with diabetes (pre-gestational and gestational) and with mild hyperglycemia, from diagnosis, treatment, and pre- and postnatal care. Data collection took place from March 2016 to December 2018, where they will be analyzed later.

The ethical aspects provided for in Resolution No. 466/12 of the National Health Council will be preserved. The project was approved by the Research Ethics Committee of the Botucatu School of Medicine, UNESP, under the number CAAE 52734216.1.0000.5411, with the opinions 1,440,349 (version 1, March 7, 2016) and 2,888,954 (version 2, September 12, 2018).

Participants

All pregnant women with DM, gestational or pre-pregnancy, confirmed by (TTG100g) and/or (PG) attended at the study collection site during the data collection period were included. The pregnant women in the study were accompanied by a team composed of obstetricians specialized in high-risk pregnancies, residents, nutritionists, nurses, and neonatologists. Positive screening for gestational diabetes was considered with fasting glucose ≥ 90mg/dL and/or a risk factor; in addition to the diagnosis made by the 100g TTG and glycemic profile. The cutoff points for TTG were those proposed by Carpenter & Coustan[13,14] and for the glycemic profile those proposed by Gilmer et al.[15].

Thus, the pregnant women being followed up at the institution were randomized into three groups: The control group, without application of Reiki; the intervention group with the application of face-to-face Reiki and the remote intervention group, with the application of Reiki at a distance.

Interventions

Seven sessions of Reiki or simulation of laying on of hands were applied, in person or at a distance, in pregnant women with diabetes prior to pregnancy and gestational diabetes.

The face-to-face intervention group received medical and nursing treatment like the control, however, Reiki was applied during pregnancy for 7 face-to-face sessions after the diagnosis of gestational diabetes or pregnancy. The sessions were applied individually by the student responsible for this project, with experience in Reiki Therapy and with authorization from the pregnant woman through the consent form for free clarification. Reiki sessions were scheduled on the same day the pregnant woman returned for prenatal care, with the duration of each session lasting 30 minutes.

The remote intervention group received medical and nursing treatment like the control, however, Reiki was applied during pregnancy for 7 remote sessions, after the diagnosis of gestational diabetes or pregnancy. The sessions were applied individually by the student responsible for this project, with experience in Reiki Therapy, and with authorization from the pregnant woman through the consent form for free clarification.

The remote Reiki sessions were scheduled on the same day the pregnant woman returned for prenatal care, with the duration of each session lasting 30 minutes.

Participants in the control group received medical and nursing care during pregnancy and at the time of delivery, according to the protocol established by the institution, as well as the intervention group, the control received a simulation of laying on of hands (simulation of Reiki therapy). This mimicry occurred with the same touch movements as the intervention group, however without knowledge of Reiki practice. The process of Reiki therapy was extremely equal in all groups and only the research members knew who was from the control and intervention groups, but the patients did not have access to such information.

Outcomes

Pregnant women were evaluated at two times during the experiment:

- T1 – corresponding to the first prenatal consultation for pregnant women with type 1 Diabetes mellitus (DM1) and type 2 Diabetes mellitus (DM2) or to the diagnosis of the disease, for pregnant women with Gestational Diabetes mellitus (GDM).
- T2 – corresponding to hospitalization for childbirth when all pregnant women with diabetes were evaluated.

In both moments of evaluation, three questionnaires administered by the interviewer and/or self-administered, duly validated for all pregnant women included in the study, were applied to measure quality of life, anxiety, and depression. The instruments were the Whoqol–Bref to assess quality of life, Beck Depression Inventory and Anxiety Inventory.

The WHOQOL BREF contains 26 questions comprising four fields: physical, psychological, social relationships and environment[16]. The Beck Depression Inventory, consisting of 21 items, each with four alternatives, with scores from 0 to 3, with 3 being the worst condition. The total score is the result of the sum of the individual scores of the items (maximum of 63 points) and allows the classification of depression intensity levels (10-18 points: mild; 19-29: moderate; ≥ 30: severe)[17]; the anxiety inventory – trait and state, composed of two scales to assess the anxious state and the anxious trait. Each is made up of 20 statements (each with a scale of 1 to 4 points). Thus, the total score of one of these two scales can range from 20 to 80 points; scores of 20-30 points indicate a low level of anxiety; 31-49 points, medium level and ≥ 50 points, high level of anxiety[18].

Data were collected from mothers for: type of vaginal delivery, blood glucose levels, maternal death, gestational age greater than or equal to 37 weeks of gestation until birth, time, and number of consultations during pregnancy. In addition, data from newborns were collected, such data referring to the care provided: clinical history with gestational age (weeks) at birth, Apgar score, birth weight, classification of gestational age at birth (term or preterm), classification of newborn weight by gestational age (adequate for gestational age=AGA, small for gestational age=SGA and large for gestational age=GIG), type of care (rooming, nursery and NICU) and perinatal death.

Sample size

The sample consisted of pregnant women who had pre-gestational diabetes and gestational diabetes during prenatal care. Pregnant women with pre-pregnancy and gestational diabetes were randomized into control and intervention. The sample size corresponded to the number of pregnant women with pre-gestational and gestational diabetes who were attended from March 2016 to December 2018. The population was 150 diabetic pregnant women attended during the period (the service serves about 50 diabetic patients per year); therefore 50 patients will be seen with face-to-face Reiki therapy, 50 with distance Reiki therapy and 50 without therapeutic intervention (control/placebo group).

Randomization

Randomization was performed using validated software accessible on the website www.randomization.com by Staepe/FMB. The confidentiality of the list was maintained through opaque envelopes so that the investigators responsible for the inclusion of patients had no way of predicting which group the patient was allocated to. The copy of this randomization is under the custody of Staepe of FMB/UNESP.

Statistical methods

The data obtained will be entered into an Excel spreadsheet and submitted to statistical analysis. Initially, a descriptive analysis will be performed with the calculation of mean and standard deviation for quantitative variables and frequencies and percentages for variables categorized in general and stratified by group.

Comparisons of means will be made using ANOVA followed by Tukey's multiple comparison test for data that presented normal distribution. For data with skewed

distribution, the comparison of means will be made by fitting a gamma distribution followed by Wald's multiple comparison test.

For count data, comparisons will be made using Poisson regression followed by Wald's multiple comparison test. The associations of categorized variables with groups will be made using the chi-square test. Data analysis of the questionnaires was performed using a repeated measures design evaluating the interaction groups versus moments using ANOVA followed by Tukey's multiple comparison test. In all tests, the significance level of 5% or the p-value was fixed. All analyzes will be done by the SAS for Windows, v.9.4 software.

Discussion

There are few works in the literature on Reiki in the field of obstetrics. The FMB Diabetes and Pregnancy Research Group conducted a systematic review of the effectiveness of Reiki in pregnant women to reduce pain during childbirth (cesarean section). In this review, only one study on the subject was found, which did not show strong evidence of the influence of Reiki in reducing pain during labor[19].

A study that aimed to assess how pregnant women diagnosed with diabetes understand and accept the use of integrative and complementary practices in health, especially Reiki, during prenatal care identified that pregnant women have knowledge of some integrative and complementary practices in health and that they would receive such therapies if they were available in the Unified Health System, but Reiki therapy proved to be unknown among patients. Thus, there is a need for a study to introduce integrative and complementary therapies in Brazilian public health, especially in the context of pregnant women[11].

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